

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

OPIATE LITIGATION

This document relates to:

Track Three Cases

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS' LIMITED REPLY IN OPPOSITION TO
DEFENDANTS' RESPONSES TO PLAINTIFFS' CLOSING BRIEF**

In their responses to Plaintiffs' Closing Brief for Phase 2 Trial (Dkt. #4513), Defendants include a new argument unrelated to the scope of abatement or injunctive relief. Specifically, they argue that a recent Supreme Court decision, which addresses the requisite *mens rea* to criminally convict defendants under § 841 of the Controlled Substances Act, requires this Court to enter a directed verdict on nuisance liability in favor of Defendants, or, alternatively, to order a new trial on liability. Dkt. #4569 (WAG/WMT Resp. to Ps' Closing Brief) at pp. 51-54 (citing *Ruan v. U.S.*, 142 S. Ct. 2370, 2022 WL 2295024 (2022)); Dkt. #4570 (CVS Resp. to Ps' Closing Brief) at pp. 25-26 (same). Defendants' arguments are without merit, as *Ruan* has no bearing on Plaintiffs' claims in this case.

In *Ruan*, the Supreme Court interpreted § 841(a) in the context of a criminal prosecution. 2022 WL 2295024. Specifically, § 841 “makes it a federal crime, ‘[e]xcept as authorized[,] . . . for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance,’ such as opioids.” *Id.* at *3 (emphasis omitted) (quoting 21 U.S.C. § 841(a)). *Ruan* involved two cases in which the government prosecuted and convicted two doctors for “dispensing controlled substances not ‘as authorized[,]’” in violation of § 841. *Id.* The issue on appeal was whether the “knowingly or intentionally” requirement of § 841(a) applied to the “except as authorized” clause. *Id.* at *5. The Supreme Court answered affirmatively, holding that once a criminal defendant “meets the burden of producing evidence that his or her conduct was ‘authorized,’ the Government must prove beyond a reasonable doubt that the defendant knowingly

or intentionally acted in an unauthorized manner.” *Id.* The court reasoned that applying the “‘knowingly or intentionally’ *mens rea*” to authorization was consistent with well-established principles underlying the interpretation of *criminal* statutes. *Id.* at *5 (“[A]s a general matter, our *criminal* law seeks to *punish* the vicious will. With few exceptions, wrongdoing must be conscious to be *criminal*. . . . Consequently, when we interpret *criminal* statutes, we normally start from a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state.”) (cleaned up; internal citations omitted) (emphasis added).¹

The present case is a civil tort action, not a criminal prosecution. Conduct can violate the CSA even if it does not subject the violator to criminal liability. For example, all registrants are required to “provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 C.F.R. § 1301.71(a). Significantly, there is no “knowledge” component to that regulation. And even if there was (which there is not), Plaintiffs adduced ample evidence at trial that Defendants knowingly and intentionally failed to provide effective controls against diversion. *See, e.g.*, Dkt. #4241 (Ps’ Opp. to Ds’ Rule 50(b) Motions) at pp. 24-43, 47-64, 67-82; Dkt. #4295 (Order Denying Ds’ Rule 50(b) Motions) at p. 6 (“[T]he evidence introduced

¹ *See also id.* at *6 (“A strong scienter requirement helps to diminish the risk of ‘overdeterrence,’ *i.e.*, *punishing* acceptable and beneficial conduct that lies close to, but on the permissible side of, the *criminal* line.”) (emphasis added), *8 (rejecting substitute *mens rea* standard proposed by government, under which a defendant could be convicted under § 841 if the government proves that he “did not even make an objectively reasonable attempt to ascertain and act within the bounds of professional medicine”: “For one thing, § 841, like many *criminal* statutes, uses the familiar *mens rea* words ‘knowingly or intentionally.’ It nowhere uses words such as ‘good faith,’ ‘objectively,’ ‘reasonable,’ or ‘honest effort.’ For another, the Government’s standard would turn a defendant’s *criminal* liability on the mental state of a hypothetical ‘reasonable’ doctor, not on the mental state of the defendant himself or herself. We have rejected analogous suggestions in other *criminal* contexts.”) (internal citation omitted) (emphasis added), *8 (noting it has “long been reluctant to infer that a negligence standard was intended in *criminal* statutes”) (citations omitted) (emphasis added), *9 (“[F]or purposes of a *criminal* conviction under § 841, this requires proving that a defendant knew or intended that his or her conduct was unauthorized.”) (emphasis added).

at trial was sufficient for a jury to reasonably conclude Plaintiffs demonstrated that each Defendant knowingly engaged in unlawful dispensing conduct.”²

Unsurprisingly, Defendants completely ignore § 1301.71(a). Instead they point to 21 C.F.R. § 1306.04(a), claiming that “*Ruan’s* logic applies equally to” that regulatory provision. Dkt. #4569 (WAG/WMT Resp. to Ps’ Closing Brief) at p. 52. But it is clear from § 1306.04(a) that the “knowingly” clause of that regulation specifically relates to criminal liability:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person *knowingly* filling such a purported prescription, as well as the person issuing it, *shall be subject to the penalties* provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a) (emphasis added). Again, this is not a criminal action and, contrary to Defendants’ assertions, a nuisance abatement award is not a “penalty.” *See* Dkt. #4571 (Ps’ Resp. to Ds’ Closing Briefs) at pp. 40-41, 67-68.

² Defendants cherry-pick a single word from Plaintiffs’ counsel’s closing argument to claim that Plaintiffs “argued to the jury that Defendants could be held liable even with ‘superb’ dispensing based merely on the volume of medications dispensed.” Dkt. #4569 (WAG/WMT Resp. to Ps’ Closing Brief) at p. 53. In actuality, Plaintiffs’ counsel used the word when explaining how Defendants *intentionally* caused a public nuisance: “I’ve got to show either one of two things. I have got to show that either the defendant engaged in intentional conduct that caused a significant and ongoing interference with this public right, or that they engaged in unlawful conduct with the same result. I think we’ve done both. The intentional element is certainly met. They weren’t accidentally dispensing opiates. They knew what they were doing. . . . *The conduct, poor, inadequate, or superb, was intentional conduct each step along the way.*” Dkt. #4153 (11/15/21 Trial Tr.) at 7169:8-21 (emphasis added). Additionally, contrary to Defendants’ assertions, Plaintiffs did not argue that Defendants could be held liable simply for dispensing large volumes of opioids. Rather, they argued (and demonstrated) that Defendants unlawfully and intentionally dispensed large volumes of opioids presenting one or more red flags without sufficiently resolving those red flags prior to dispensing, making it likely that large numbers of those opioids were diverted. *See, e.g.,* Dkt. #4241 (Ps’ Opp. to Ds’ Rule 50(b) Motions) at pp. 24-43, 47-64, 67-82.

Regardless, the jury in this case was specifically instructed that “[a] violation of the corresponding responsibility occurs when a person *knowingly* fills or allows to be filled an illegitimate prescription[,]” and that “[i]n this context, knowingly includes when a person acts with *deliberate* ignorance or *willful* blindness to information in their possession.” Dkt. #4153 (11/15/21 Trial Tr.) at 7076:2-6 (emphasis added). This Court has already determined that these instructions provide an accurate description of the law and that Defendants’ objections to them “are not well taken.” Dkt. #4296 (Order Denying Ds’ MNTs) at p. 66 & fns. 58-59; *see also* Dkt. #4295 (Order Denying Ds’ Rule 50(b) Motions) at pp. 41, 44. Even if *Ruan* was applicable to this case (which it is not), nothing in that opinion indicates that these instructions are incorrect.³

For these reasons, Defendants’ arguments that *Ruan* requires a directed verdict or new trial in this case should be rejected.

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Respectfully submitted,

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³ The *Ruan* court certainly never stated that evidence of the doctors’ deliberate ignorance or willful blindness could not satisfy § 841’s knowledge requirement. Rather, the court acknowledged: “The Government, of course, can prove knowledge of a lack of authorization through circumstantial evidence. And the regulation defining the scope of a doctor’s prescribing authority does so by reference to objective criteria such as ‘legitimate medical purpose’ and ‘usual course’ of ‘professional practice.’ As we have said before, ‘the more unreasonable’ a defendant’s ‘asserted beliefs or misunderstandings are,’ especially as measured against objective criteria, ‘the more likely the jury . . . will find that the Government has carried its burden of proving knowledge.’” 2022 WL 2295024, at *9 (internal citations omitted).

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CERTIFICATE OF SERVICE

I hereby certify that on July 14, 2022, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

/s/Peter H. Weinberger

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